MUCINEX SINUS-MAX SEVERE CONGESTION RELIEF CLEAR AND COOL-
acetaminophen, guaifenesin, and phenylephrine hydrochloride solution
Reckitt Benckiser LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Mucinex® Sinus-Max®
Severe Congestion Relief Clear & Cool™

Drug Facts

Active ingredients (in each 20 mL)	*Purposes*
Acetaminophen 650 mg	**Pain reliever**
Guaifenesin 400 mg	Expectorant
Phenylephrine HCl 10 mg	Nasal decongestant

Uses

- temporarily relieves:
  - nasal congestion
  - headache
  - minor aches and pains
  - sinus congestion and pressure
- temporarily promotes nasal and/or sinus drainage
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 6 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

Allergy alert

Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- liver disease
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

When using this product do not use more than directed

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back, or occurs with rash or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not take more than directed (see Overdose warning)**
- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- adults and children 12 years of age and older: 20 mL in dosing cup provided every 4 hours
- children under 12 years of age: do not use

Other information

- each 20 mL contains: **sodium 9 mg**
- store between 20-25°C (68-77°F)
- dosing cup provided
- do not refrigerate

Inactive ingredients

anhydrous citric acid, D&C yellow no. 10, edetate disodium, FD&C blue no. 1, flavors, glycerin, propyl gallate, propylene glycol, sodium benzoate, sodium citrate, sorbitol, sucralose, water, xanthan

gum

Questions?

1-866-MUCINEX (1-866-682-4639)

You may also report side effects to this phone number.

Dist. by: Reckitt Benckiser
Parsippany, NJ 07054-0224
Made in England

PRINCIPAL DISPLAY PANEL - 180 mL Bottle Label

NDC 63824-265-66

MAXIMUM STRENGTH*

Mucinex®
SINUS-MAX®

SEVERE CONGESTION
RELIEF

CLEAR & COOL™

Acetaminophen – Pain Reliever
Guaifenesin – Expectorant
Phenylephrine HCl – Nasal Decongestant

- **Clears Sinus Congestion**
- **Relieves Headache**
- **Thins & Loosens Mucus**

6 FL OZ (180mL)
FOR AGES 12+

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Drug Facts (continued)

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- cough comes back, or occurs

▶

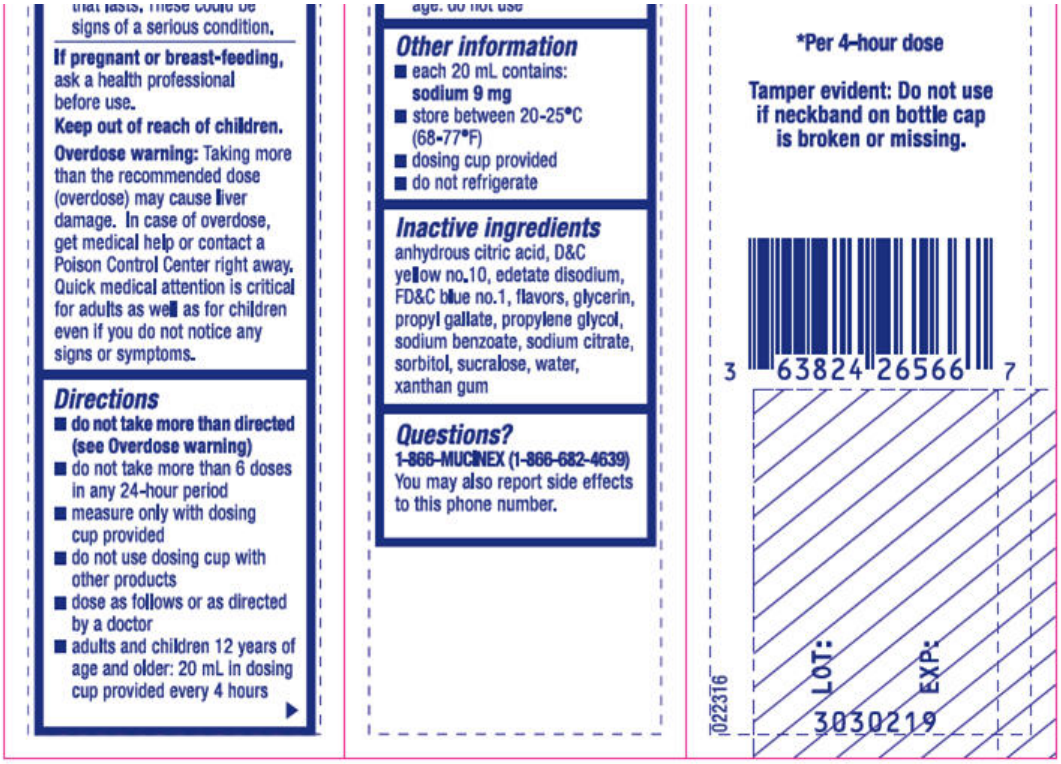
Drug Facts (continued)

with rash or headache that lasts. These could be

Drug Facts (continued)

- children under 12 years of age: do not use

PEEL CORNER TO READ COMPLETE DRUG FACTS AND INFORMATION



MUCINEX SINUS-MAX SEVERE CONGESTION RELIEF CLEAR AND COOL

acetaminophen, guaifenesin, and phenylephrine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63824-265

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
D&C yellow no. 10 (UNII: 35SW5USQ3G)	
edetate disodium (UNII: 7FLD91C86K)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
glycerin (UNII: PDC6A3C0OX)	
propyl gallate (UNII: 8D4SNN7V92)	
propylene glycol (UNII: 6DC9Q167V3)	
sodium benzoate (UNII: OJ245FE5EU)	
sodium citrate, unspecified form (UNII: 1Q73Q2JULR)	
sorbitol (UNII: 506T60A25R)	
sucralose (UNII: 96K6UQ3ZD4)	
water (UNII: 059QF0KO0R)	
xanthan gum (UNII: TTV12P4NEE)	

Product Characteristics

Color	GREEN	**Score**	
Shape		**Size**	
Flavor	MENTHOL	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-265-66	180 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	07/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/01/2016	

Labeler - Reckitt Benckiser LLC (094405024)

Revised: 5/2016 Reckitt Benckiser LLC